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Exhibit 1

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BEFORE THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES OF THE STATE OF MONTANA

In the matter of the amendment of ARM 37.86.1101 and 37.86.1105 pertaining to medicaid outpatient drug reimbursement	)))))	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT

TO: All Interested Persons

1. On May 16, 2002, at 1:30 p.m., a public hearing will be held in Room 107 of the Department of Public Health and Human Services Building, 111 N. Sanders, Helena, Montana to consider the proposed amendment of the above-stated rules.

The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who need an alternative accessible format of this notice or provide reasonable accommodations at the public hearing site. If you need to request an accommodation, contact the department no later than 5:00 p.m. on May 10, 2002, to advise us of the nature of the accommodation that you need. Please contact Dawn Sliva, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, MT 59604-4210; telephone (406)444-5622; FAX (406)444-1970; Email dphhslegal@state.mt.us.

2. The rules as proposed to be amended provide as follows. Matter to be added is underlined. Matter to be deleted is interlined.

37.86.1101 OUTPATIENT DRUGS, DEFINITIONS (1) "Estimated acquisition cost (EAC)" means the cost of drugs for which no maximum allowable cost (MAC) price has been determined. The EAC is the department's best estimate of what price providers are generally paying in the state for a drug in the package size providers buy most frequently. The EAC for a drug is:

(a) the direct price (DP) charged by manufacturers to retailers;

(b) if there is no available DP for a drug or the department determines that the DP is not available to providers in the state, the EAC is the average wholesale price (AWP) less ~~10%~~ 15%; or

(c) through (4) remain the same.

AUTH: Sec. 53-2-201 and 53-6-113, MCA
IMP: Sec. 53-2-201, 53-6-101, 53-6-111 and 53-6-113, MCA

37.86.1105 OUTPATIENT DRUGS, REIMBURSEMENT (1) remains the same.

MAR Notice No. 37-233

(2) The dispensing fee for filling prescriptions shall be determined for each pharmacy provider annually.

(a) remains the same.

(b) The dispensing fees assigned shall range between a minimum of $2.00 and a maximum of ~~$4.20~~ $4.35.

(c) and (d) remain the same.

(3) In-state pharmacy providers that are new to the Montana medicaid program will be assigned an interim $3.50 dispensing fee until a dispensing fee questionnaire, as provided in (2) above, can be completed for 6 months of operation. At that time, a new dispensing fee will be assigned which will be the lower of the dispensing fee calculated in accordance with (2) for the pharmacy or the ~~$4.20~~ $4.35 dispensing fee. Failure to comply with the 6 months dispensing fee questionnaire requirement will result in assignment of a dispensing fee of $2.00.

(4) through (5)(b) remain the same.

AUTH: Sec. 53-2-201 and 53-6-113, MCA
IMP: Sec. 53-6-101, 53-6-113 and 53-6-141, MCA

3. The Montana Medicaid Program pays medical expenses for eligible low income and medically needy individuals. Medical providers enrolled in the Montana Medicaid Program are reimbursed for services provided to Medicaid recipients as set forth in the rules governing the Medicaid Program.

ARM 37.86.1101 through 37.86.1105 address issues relating to outpatient drugs, that is, drugs furnished outside of a hospital. ARM 37.86.1101 defines terms used in the outpatient drug rules, and ARM 37.86.1105 regulates reimbursement for outpatient drugs.

The amendment of ARM 37.86.1101 and 37.86.1105 is now necessary to implement changes in the amount the Department will pay for outpatient drugs in certain circumstances. ARM 37.86.1105 provides that the Department pays for drugs on the basis of either the estimated acquisition cost (EAC) or the maximum allowable cost (MAC) of the drug plus a dispensing fee, or the provider's usual and customary charge for the drug, whichever is lowest.

Subsection (1)(b) of ARM 37.86.1101 currently states that the EAC is the direct price charged by manufacturers to retailers but further provides that when there is no direct cost for a drug, the EAC will be the average wholesale price less 10%. The Department proposes to amend subsection (1)(b) of ARM 37.86.1101 to state that in the latter case the EAC of a drug will be the average wholesale price reduced by 15% rather than 10%. ARM 37.86.1105(2)(b) currently provides that the dispensing fee which comprises part of the reimbursement for outpatient drugs shall be a minimum of $2.00 and a maximum of $4.20. The Department proposes to amend subsection (2)(b) to increase the maximum dispensing fee from $4.20 to $4.35. Subsection (3) of

this rule also refers to the $4.20 maximum dispensing fee so it is also being amended to reflect the increase to $4.35.

These changes are being implemented for budgetary reasons. Prescription drugs are among the most costly Medicaid services and expenditures for drugs continue to rise. Costs to the pharmacy program increased 17% last year, which results in a projected budget of $78 million for state fiscal year 2002. If costs continue to increase at that rate, the pharmacy budget is expected to be over $94 million in state fiscal year 2003 and over $136 million by the end of the next biennium, state fiscal year 2005. One of the ways the Department may be able to control costs would be to develop reimbursement methodologies that were more in line with actual drug costs.

The Estimated Acquisition Cost (EAC) for Montana is calculated by using the Average Wholesale Price (AWP) for a drug less a percentage discount (AWP less 10%). The AWP is the price assigned to the drug by its manufacturer and is compiled for Montana Medicaid by First DataBank.

The current EAC (AWP less 10%) methodology has been in place since 1988. Since that time, the Office of Inspector General (OIG) has conducted two studies to determine the actual acquisition cost of brand name and generic drugs. In 1997, the OIG issued a report that showed average discounts of 18.30% below AWP and 42.45% below AWP, respectively. Again in 2000, the OIG conducted another study which showed that nationally, pharmacy actual acquisition cost was an average of 21.84% below AWP. As a result of these studies, the OIG recommended that the Centers for Medicare and Medicaid Services (CMS) require the States to bring pharmacy reimbursement for brand name drugs more in line with the actual acquisition cost which they identified as being 21.84% below AWP.

Additionally, the OIG studied actual acquisition cost in Montana and found that the overall estimate of the discount below AWP on invoice prices was 19.71% for brand name drugs and 65.37% for generic drugs. Again, the OIG recommended that the State Agency consider the results of this review as a factor in determining any future changes to pharmacy reimbursement for Medicaid drugs.

It is important to note that while the OIG claims the discount below AWP is 19.71% and 65.37%, the Department does not wish to reduce reimbursement to those exact levels. The Department believes that the study failed to account for the cost of professional services and the cost of dispensing which includes supplies and staff. Therefore, the Department bases its recommendations in part on the OIG study as well as analysis of the implications to the overall pharmacy budget.

Because Medicaid programs in nearly all states are experiencing escalating costs, the Department has also analyzed reimbursement formulas among the other states. Many states are heeding the

recommendations of the OIG study and are changing their reimbursement rates, including: Arkansas, Colorado, Connecticut, Florida, Idaho, Illinois, Maryland, Mississippi, Nebraska, North Carolina, Oklahoma, Oregon, Texas, Virginia, Washington, West Virginia, and Wyoming.

The Department feels that in order to make the reduction to providers most palatable, the dispensing fee should increase to bring it in line with the average dispensing fee among other states in the country. Currently, the average dispensing fee is $4.35 (based on a survey conducted by Indiana Medicaid in September, 2001). In states surrounding Montana, the dispensing fee ranges from $3.80 in Oregon to $5.00 in Wyoming. Idaho's dispensing fee is $4.94; Washington's dispensing fee is $5.02; North Dakota's dispensing fee is $4.60 and South Dakota's dispensing fee is $4.75.

The alternative is to not implement this change to the reimbursement methodology. The Department is employing as many strategies as are realistic for cost containment, including prior authorization, mandatory generic substitution, and drug utilization review. However, because drug expenditures continue to rise, the alternative to changing the reimbursement methodology is to continue to make across the board cuts (as was employed January 1, 2002 through June 30, 2002). Across the board cuts prove to be more punitive to pharmacy providers because in some cases, the cuts result in pharmacies being reimbursed below their actual cost when providers bill using their acquisition cost as their usual and customary charge. By taking into account the actual acquisition cost, as is demonstrated in the OIG reports, the Department can more accurately reimburse providers for their services.

This decrease in reimbursement and increase in dispensing fees will result in approximately savings of $2.6 million (based on FY 2001). However, the Department can expect the savings to change as the figures are projected forward. The change to the percentage below AWP would affect all Medicaid pharmacy providers (nearly 450 pharmacy providers).

4. Interested persons may submit their data, views or arguments either orally or in writing at the hearing. Written data, views or arguments may also be submitted to Dawn Sliva, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, MT 59604-4210, no later than 5:00 p.m. on May 23, 2002. Data, views or arguments may also be submitted by facsimile (406) 444-1970 or by electronic mail via the Internet to dphhslegal@state.mt.us. The Department also maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. For placement on the mailing list, please write the person at the address above.

5. The Office of Legal Affairs, Department of Public Health and Human Services has been designated to preside over and conduct the hearing.

Dawn Sliva
Rule Reviewer

Director, Public Health and Human Services

Certified to the Secretary of State April 15, 2002.

Exhibit 2

Case 1:01-cv-12257-PBS Document 3773-2 Filed 02/08/07 Page 8 of 32

Home IV State Plan

Methods & Standards
for Establishing
Payment Rates,
Services 12 a.,
Outpatient Drug Services

Reimbursement for drugs shall not exceed the lowest of:

1. The Estimated Acquisition Cost (EAC) of the drug plus a dispensing fee, or;

2. The Federal Upper Limit (FUL), Maximum Allowable Cost (MAC) of the drug, in the case of multi-source (generic), plus a dispensing fee, or;

3. The provider's usual and customary charge of the drug to the general public.

Exception: The FUL or MAC limitation shall not apply in a case where a physician certifies in his/her own handwriting the specific brand is medically necessary for a particular recipient. An example of an acceptable certification is the handwritten notation "Brand Necessary" or "Brand Required." A check off box on a form or rubber stamp is not acceptable.

The EAC is established by the state agency using the Federal definition of EAC as a guideline: that is, "Estimated Acquisition Cost" means the state agency's best estimate of what price providers generally pay for a particular drug.

The EAC, which includes single source, brand necessary and drugs other than multi-source, is established using the following methodology:

Drugs paid by their Average Wholesale Price (AWP) will be paid at AWP less 10%. The policy for the reimbursement of Direct Price (DP) drugs (the price charged by manufacturers to retailers) is the current direct price (the direct price in effect on the date of service for the claim.

The MAC for multiple source drugs will not exceed the total of the dispensing fee established by the Department and an amount that is equal to 150 percent of the price established under the methodology set forth in 42 CFR 447.331 and 447.332 for the least costly therapeutic equivalent.

A variable dispensing fee will be established by the state agency, by using the results of a cost survey of pharmacy's operational costs. A pharmacy may be assigned an enhanced dispensing fee to cover the additional costs associated with packaging "unit dose" prescriptions.

Provider dispensing fee(s) are available on-line in the Medicaid Management Information System (MMIS) provider file and in the Medicaid Prescription Drug Card System (PDCS) provider plan file.

MT 023015

Exhibit 3

MONTANA

Reimbursement for drugs shall not exceed the lowest of:

1. The Estimated Acquisition Cost (EAC) of the drug plus a dispensing fee, or;
2. The Federal Upper Limit (FUL), Maximum Allowable Cost (MAC) of the drug, in the case of mutli-source (generic), plus a dispensing fee, or;
3. The provider's usual and customary charge of the drug to the general public.

Exception: The FUL or MAC limitation shall not apply in a case where a physician certifies in his/her own handwriting the specific brand is medically necessary for a particular recipient. An example of an acceptable certification is the handwritten notation "Brand Necessary" or "Brand Required." A check off box on a form or rubber stamp is not acceptable.

Exception: For outpatient drugs provided to medicaid recipients in state institutions, reimbursement will conform to the state contract for pharmacy services; or for institutions not participating in the state contract for pharmacy services, reimbursement will be the actual cost of the drug and dispensing fee. In either case, reimbursement will not exceed, in the aggregate, the EAC or the MAC plus the dispensing fee.

The EAC is established by the state agency using the Federal definition of EAC as a guideline: that is, "Estimated Acquisition Cost" means the state agency's best estimate of what price providers generally pay for a particular drug.

The EAC, which includes single source, brand necessary and drugs other than multi-source, is established using the following methodology:

- The Direct Price (DP), the price charged by manufacturers to retailers, will be paid unless the DP is not available to providers in the state. If no DP is available, drugs paid by their Average Wholesale Price (AWP) will be paid at AWP less 10%. If the state agency determines that acquisition cost is lower than either the available DP or AWP less 10%, then the state agency may set an allowable acquisition cost based on data provided by the drug pricing file contractor.

The MAC for multiple source drugs will not exceed the total of the dispensing fee established by the Department and an amount that is equal to 150 percent of the price established under the methodology set forth in 42 CFR 447.331 and 447.332 for the least costly therapeutic equivalent.

A variable dispensing fee will be established by the state agency, by using the results of a cost survey of pharmacy's operational costs. A pharmacy may be assigned an enhanced dispensing fee to cover the additional costs associated with packaging "unit dose" prescriptions.

Provider dispensing fee(s) are available on-line in the Medicaid Management Information system (MMIS) provider file and in the Medicaid Prescription Drug Card System (PDCS) provider plan file.

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Exhibit 4

ARTMENT OF HEALTH AND HUMAN SERVICES
EALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 02-003 (revised)

2. STATE: MONTANA

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

O: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
01 OCTOBER 2002

TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

FEDERAL STATUTE/REGULATION CITATION:
42 CFR 447.331

7. FEDERAL BUDGET IMPACT:
a. FFY 2003 $ 2,114,011
b. FFY 2004 $ 2,434,992

PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 4.19B, services 12a,
Outpatient Drug Services

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Same

RECEIVED
MAY 12 2003
HEALTH POLICY & SERVICES

). SUBJECT OF AMENDMENT:
Outpatient Drug Services

. GOVERNOR'S REVIEW *(Check One)*:

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☒ OTHER, AS SPECIFIED:
Single State Agency Director

. SIGNATURE OF STATE AGENCY OFFICIAL:
Gail Gray

. TYPED NAME:
Gail Gray

. TITLE:
Director

. DATE SUBMITTED:

16. RETURN TO:
Montana Department of HeALTH and Human Svcs
Attn: Karl Clark
PO Box 202951
Helena, MT 59620-2951

FOR REGIONAL OFFICE USE ONLY

7. DATE RECEIVED:
October 22, 2002

18. DATE APPROVED:
March 7, 03

PLAN APPROVED - ONE COPY ATTACHED

). EFFECTIVE DATE OF APPROVED MATERIAL:
October 1, 2002

20. SIGNATURE OF REGIONAL OFFICIAL

. TYPED NAME:
Mark Gilbert

22. TITLE:
Associate Regional Administrator

. REMARKS:

POSTMARK: October 21, 2002

MT 024346

ORM HCFA-179 (07-92)

Instructions on Back

MONTANA

Reimbursement for drugs shall not exceed the lowest of:

1. The Estimated Acquisition Cost (EAC) of the drug plus a dispensing fee, or;
2. The Federal Upper Limit (FUL), Maximum Allowable Cost (MAC) of the drug, in the case of mutli-source (generic), plus a dispensing fee, or;
3. The provider's usual and customary charge of the drug to the general public.

Exception: The FUL or MAC limitation shall not apply in a case where a physician certifies in his/her own handwriting the specific brand is medically necessary for a particular recipient. An example of an acceptable certification is the handwritten notation "Brand Necessary" or "Brand Required." A check off box on a form or rubber stamp is not acceptable.

Exception: For outpatient drugs provided to Medicaid recipients in state institutions, reimbursement will conform to the state contract for pharmacy services; or for institutions not participating in the state contract for pharmacy services, reimbursement will be the actual cost of the drug and dispensing fee. In either case, reimbursement will not exceed, in the aggregate, the EAC or the MAC plus the dispensing fee.

The EAC is established by the state agency using the Federal definition of EAC as a guideline: that is, "Estimated Acquisition Cost" means the state agency's best estimate of what price providers generally pay for a particular drug.

The EAC, which includes single source, brand necessary and drugs other than multi-source, is established using the following methodology:

The Direct Price (DP), the price charged by manufacturers to retailers, will be paid unless the DP is not available to providers in the state. If no DP is available, drugs paid by their Average Wholesale Price (AWP) will be paid at AWP less 15 percent. If the state agency determines that acquisition cost is lower than either the available DP or AWP less 15 percent, then the state agency may set an allowable acquisition cost based on data provided by the drug pricing file contractor.

The MAC for multiple source drugs will not exceed the total of the dispensing fee established by the Department and an amount that is equal to 150 percent of the price established under the methodology set forth in 42 CFR 447.331 and 447.332 for the least costly therapeutic equivalent.

A variable dispensing fee will be established by the state agency. The dispensing fee is based on the pharmacy's average cost of filling a prescription. The average cost of filling a prescription will be based on the direct and indirect costs that can be allocated to the cost of the prescription department and that of filling a prescription, as determined from the Montana dispensing fee questionnaire. A provider's failure to submit, upon request, the dispensing fee questionnaire properly completed will result in the assignment of the minimum dispensing fee offered. A copy of the Montana dispensing fee questionnaire is available upon request from the department.

MONTANA

Dispensing fees shall be established as follows:

1. The dispensing fees assigned shall range between a minimum of $2.00 and a maximum of $4.70.
2. Out-of-state providers will be assigned a $3.50 dispensing fee.
3. If the individual provider's usual and customary average dispensing fee for filling prescription is less than the foregoing method of determining the dispensing fee, then the lesser dispensing fee shall be applied in the computation of the payment to the pharmacy provider.

In-state pharmacy providers that are new to the Montana Medicaid program will be assigned an interim $3.50 dispensing fee until a dispensing fee questionnaire can be completed for six months of operation. At that time, a new dispensing fee will be assigned which will be the lower of the dispensing fee calculated for the pharmacy or the $4.70 dispensing fee. Failure to comply with the six months dispensing fee questionnaire requirement will result in assignment of a dispensing fee of $2.00.

An additional

~~A separate~~ dispensing fee of $0.75 will be paid for "unit dose" prescriptions. This "unit dose" dispensing fee will offset the additional cost of packaging supplies and materials which are directly related to filling "unit dose" prescriptions by the individual pharmacy and is in addition to the regular dispensing fee allowed. Only one unit dose dispensing fee will be allowed each month for each prescribed medication. A dispensing fee will not be paid for a unit dose prescription packaged by the drug manufacturer.

2/27/03

P&I change Requested by the State

Exhibit 5

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the amendment of ARM 37.86.1101 and 37.86.1105 pertaining to medicaid outpatient drug reimbursement	)))))	NOTICE OF AMENDMENT

TO: All Interested Persons

1. On April 25, 2002, the Department of Public Health and Human Services published notice of the proposed amendment of the above-stated rules at page 1257 of the 2002 Montana Administrative Register, issue number 8.

2. The Department has amended ARM 37.86.1101 as proposed.

3. The Department has amended the following rule as proposed with the following changes from the original proposal. Matter to be added is underlined. Matter to be deleted is interlined.

37.86.1105 OUTPATIENT DRUGS, REIMBURSEMENT (1) remains as proposed.

(2) The dispensing fee for filling prescriptions shall be determined for each pharmacy provider annually.

(a) remains as proposed.

(b) The dispensing fees assigned shall range between a minimum of $2.00 and a maximum of ~~$4.35~~ $4.70.

(c) and (d) remain as proposed.

(3) In-state pharmacy providers that are new to the Montana medicaid program will be assigned an interim $3.50 dispensing fee until a dispensing fee questionnaire, as provided in (2) above, can be completed for six months of operation. At that time, a new dispensing fee will be assigned which will be the lower of the dispensing fee calculated in accordance with (2) for the pharmacy or the ~~$4.35~~ $4.70 dispensing fee. Failure to comply with the six months dispensing fee questionnaire requirement will result in assignment of a dispensing fee of $2.00.

(4) through (5)(b) remain as proposed.

AUTH: Sec. 53-2-201 and 53-6-113, MCA
IMP: Sec. 53-6-101, 53-6-113 and 53-6-141, MCA

4. The Department has reviewed and considered the comments regarding the proposed change in the maximum dispensing fee. In response to comments received, the Department has decided to change the proposed increase to the dispensing fee. Whereas the Department planned to raise the maximum dispensing fee from $4.20 to $4.35, the Department agrees that the increase is too minimal to account for the cost of dispensing a

prescription. Providers strenuously objected to the notion that an increase of only $.15 would make the change to reimbursement more "palatable". Providers also regarded the insignificant increase as offensive, especially in light of dispensing fees in surrounding states. Upon further research, the Department has found that although the national average dispensing fee is $4.35, the average fee in surrounding states is much higher. Dispensing fees in Washington, Idaho, Wyoming, North Dakota and South Dakota average $4.67 (this average excludes Oregon because their dispensing fee of $3.50 is significantly lower than Montana's current fee). Therefore, the Department proposes to increase the maximum dispensing fee by $.50, which results in a maximum fee of $4.70. This change will more appropriately align Montana with surrounding states as well as recognize the cost to dispense a prescription. Additionally, the Department plans to undertake other significant cost containment measures that will require cooperation from pharmacy providers. The Department feels it is important to accurately compensate providers for the services they provide, especially when cost containment measures are enacted that may require additional assistance and time. Therefore, the Department feels the investment towards pharmacist's reimbursement is well worth the additional cost.

5. The Department has thoroughly considered all commentary received. The comments received and the Department's response to each follow:

COMMENT #1: The change to reimbursement will negatively affect all pharmacies, particularly independent, rural pharmacies. Concern was expressed about the potential impact to rural communities if pharmacies are forced out of business. Another person argued that the Office Of Inspector General (OIG) study has serious flaws and should not be considered as a basis for changes. This individual feels the change to reimbursement will negatively affect rural communities by forcing pharmacies out of business because Medicaid clients comprise nearly 40% of most pharmacies' business.

RESPONSE: The Department has considered the impact this change will have on all pharmacies in Montana, including rural pharmacies. However, the OIG Report included rural pharmacies in the study and the OIG believes that the sample design took into account the number of chain pharmacies and the number of independent pharmacies in the State and appropriately weighed the sample results.

COMMENT #2: The validity of the estimate of Average Wholesale Price (AWP) is questioned. The provider indicates he is unable to purchase drugs at the proposed levels.

RESPONSE: The Department understands that not all pharmacies may be able to purchase drugs at AWP less 15%, however, when considering all pharmacies as an aggregate, the Department is heeding the recommendation of the OIG to more accurately reflect

acquisition cost.

COMMENT #3: The Department is asking pharmacy providers to sell their merchandise at cost and subsidize the Medicaid reductions with sales on other products.

RESPONSE: The Department has no intention to force providers to subsidize Medicaid reductions with sales of other products. The Department can only be concerned about the actual acquisition cost for drugs.

COMMENT #4: The increased demand for services should result in a corresponding increase in reimbursement for providers.

RESPONSE: The Department understands that increased utilization of services requires more work for Medicaid providers. As noted above, the Department has reconsidered the increase to the dispensing fee and has approved a new maximum of $4.70.

COMMENT #5: Recipients who require expensive medications may cause the Department's budget challenges.

RESPONSE: There is no doubt that a smaller percentage of utilizing members cause the largest percentage of expenditures. However, generally, high utilizers are often most in need of medical services, including drugs. It is important to note that Medicaid exists to help serve not only the financially needy, but also the medically needy who truly have expensive health care needs. Additionally, the Department is continually striving to monitor and control high utilizers by recommending alternative and less expensive courses of treatment.

COMMENT #6: All Medicaid agencies should be subject to salary reductions to offset the budget deficit.

RESPONSE: The Department has made internal reductions in order to contain costs. Those reductions have included elimination of travel and equipment and leaving vacant positions unfilled for a period of time to restore vacancy savings. This requires consolidation of duties and requires existing staff to shoulder more of the workload at a time when administrative requirements have increased due to the demands of implementing cost containment measures.

COMMENT #7: Pharmacy providers have not had a raise in reimbursement in over ten years.

RESPONSE: The Department has increased dispensing fees twice in the last ten years: once in July 1997 when the fee increased to $4.14 and again in July 1998 when the fee increased to $4.20.

COMMENT #8: The reduction of 5% will negatively impact the discount already in place by distributors and wholesalers.

RESPONSE: The Department cannot comment on the discounts that each pharmacy may receive from their individual wholesaler or supplier because those discounts vary. The Department can only control the discount taken off the AWP.

COMMENT #9: The $.15 increase in dispensing fee is not enough to make up for the loss imposed by the change to AWP. The Department should raise the dispensing fee to the average fee found in the Northwest ($4.68). Additionally, an incentive should be provided to pharmacies for generic dispensing by paying a higher dispensing fee for generic drugs.

RESPONSE: The Department has studied the matter and has adjusted the dispensing fee as addressed in paragraph 4 of this notice.

COMMENT #10: The Department should re-evaluate who the reduction is targeted towards; pharmacists are not the reason for increased drug costs. Drug prices are falsely blamed for much of the increase in health care expenditures. However, the real reason for increase in drug expenditures is a result of the new and expensive drugs used to treat chronic diseases and the reduction in the industries' AWP. Neither of these factors can be controlled by retail or home infusion pharmacies.

RESPONSE: The Department understands that high drug costs are not the fault of pharmacies, however, only the federal government has the power to regulate the cost of drugs. The Department continues to do all we can to contain costs, including prior authorization, drug utilization review, mandatory generic substitution, tab splitting and coverage of less expensive over-the-counter drugs. Additionally, the Department continues to explore other cost saving measures to be implemented in the near future.

COMMENT #11: The profit margins for most pharmacies are only 1/3 of 1%, and that will be worsened by the Medicaid reductions. Acquisition costs of the newer, expensive drugs and highly utilized drugs are generally very high and profit margins are very low because reimbursement by insurers is low; another cut to reimbursement will cause reimbursement to be significantly below acquisition cost.

RESPONSE: The Department understands that profit margins are low for pharmacy providers just as they are for other kinds of healthcare providers. The Department would argue that we are not changing reimbursement to below cost for pharmacies; we are only trying to bring reimbursement more in line with actual acquisition costs.

COMMENT #12: It does not make sense for the Department to reduce payments to pharmacy providers because the savings the Department will gain are automatically eliminated when considering all of the factors in provider reimbursement

(federal matching dollars, state income taxes, etc).

RESPONSE: In light of the OIG study, the Department is only concerned about accurately reimbursing pharmacists based on actual acquisition cost. Although revenue is an important part of the budget equation, the Department does not have the ability to collect revenue (beyond funds we already collect from manufacturers for drug rebates).

COMMENT #13: The Department should focus on the cost of drugs or amounts of drugs utilized in order to gain cost savings.

RESPONSE: The Department is pursuing a cost containment measure to help control high utilizing clients, who typically contribute to the high expenditures in the drug program. The Department plans to implement an intensive case management model whereby we can help control drug utilization for those clients who are receiving more drugs than necessary as well as recommend (in consultation with their physician and pharmacist) less costly alternatives.

COMMENT #14: This reduction will only create more hardship for the uninsured population that is already in a difficult position.

RESPONSE: Although the Department has an interest in the overall health of all of Montana's citizens, Medicaid has an obligation to control costs for our own clients. Therefore, the Department can only try to impact those clients who are insured by Medicaid.

COMMENT #15: The Department should focus on the pharmaceutical manufacturers to cut costs, rather than providers.

RESPONSE: This comment was already addressed in Response to Comment #10. However, even though a few other states have recently pursued the development of Medicaid preferred drug lists and supplemental rebates from manufacturers, their experiences have been mired in legal controversy. At this time, the State of Montana is not willing to pursue supplemental rebates as another way to generate revenue because we are certain the State would need to spend more in legal fees trying to defend the plan than we would make in cost savings.

COMMENT #16: Strenuous objections were made to the use of the OIG reports by the Department because there are too many problems with the report including the age of the report, the small number of sample pharmacies and the urban slant on the report.

RESPONSE: As noted in a previous response and in the Department's testimony, we recognize that some entities have criticized the OIG investigation as being flawed. We agree that the OIG failed to account for the cost of professional services

and the cost of dispensing which includes supplies and staff. However, because there has not been an auditable counter-study conducted, we must base our decisions on the information provided. Because Medicaid is a public insurance benefit and is funded by both federal and state monies, one can understand how important it is that we heed the recommendations made by the OIG.

COMMENT #17: Some pharmacies indicate that the reimbursement for certain drugs are actually lower than the acquisition cost, particularly products by Pfizer and Abbott.

RESPONSE: The Department understands that pharmacies have been reimbursed below their cost for a select number of drugs made by Pfizer and Abbott. The reason for the underpayment is because selected drugs have continued to be reimbursed at direct price, when in fact direct prices are not available for the majority of pharmacies in the state, that is, pharmaceutical companies are not selling these drugs to pharmacies in Montana at the direct price. ARM 37.86.1101(1)(b) currently provides that if the direct price is not available to providers in the state, the estimated acquisition cost (EAC), on which reimbursement may be based, will be the AWP minus the discount specified in the rule. Thus, at the present time the EAC used to calculate reimbursement should be based on the AWP rather than the direct price.

For that reason, the Department has eliminated direct pricing from the reimbursement methodology effective June 5, 2002. This change will enable pharmacies to be paid at the lower of the EAC, Federal Maximum Allowable Cost (FMAC), or their usual and customary charge. Subsection (1)(a) of ARM 37.86.1101, which defines the EAC as the direct cost, is being left in the rule because the direct price may be available to pharmacies in the state at some time in the future. The Department regrets not being able to change the reimbursement methodology sooner and will allow providers who have been paid incorrectly in the past year to reverse and resubmit those claims which were previously subjected to direct pricing.

COMMENT #18: There was a time when few pharmacies participated as Medicaid providers. This reduction will again force many pharmacies to withdraw from the Medicaid system.

RESPONSE: The Department feels it is important to emphasize that we do not intend to alienate providers. The Department understands that reductions in reimbursement rates may be difficult for Medicaid providers. However, the Department does not expect the reduction in reimbursement to result in a significant impact on access to pharmacy services.

COMMENT #19: Limits should be placed on the number of people enrolled in Medicaid. Eligibility requirements should be changed, particularly so people moving from other states cannot

immediately qualify for Medicaid.

RESPONSE: In an effort to control costs throughout Medicaid, the Department will continue to examine eligibility requirements and determinations to determine who should most appropriately qualify for benefits. Additionally, the Department does undertake efforts to ensure those utilizing their health benefits are not abusing the benefits. One way the Department pursues stricter control of Medicaid individuals' care seeking is through the Restricted Card Program. Under the Restricted Card Program, Medicaid individuals who overuse the program are restricted to one physician and one pharmacy and action is taken to limit the number of unnecessary emergency room visits. If further actions are required, the Medicaid Fraud Control Unit is notified and the situation is pursued by the Department of Justice. Federal law does not permit waiting periods for medicaid recipients establishing state residency.

COMMENT #20: The number of prescriptions a person can receive in a given month should be limited.

RESPONSE: Although some states have effectively instituted script limits for their Medicaid clients, Montana Medicaid is choosing to examine a more proactive approach at this time. In the near future, the Department plans to implement an intensive case management system for high utilizing clients so we can better monitor and control drug usage. Often, there is a clinical need for a client to have more than the average number of scripts so the Department believes script limits may be more punitive than necessary. However, the Department feels that the changes to cost sharing, effective April 1, 2002, have provided incentive to clients to make informed health care choices, including how many drugs they really need.

COMMENT #21: The Department should change the cost sharing requirements so the first two prescriptions would require a 5% coinsurance. The next three prescriptions would require a 33% coinsurance and the next three would be 66%. After six prescriptions, the client would be required to pay the entire amount of the prescription.

RESPONSE: The suggestion to model cost sharing in Medicaid after a private insurance plan is a good idea. However, because Medicaid is a joint federal and state funded program, we are obligated to abide by strict regulations regarding cost sharing. Within the current Code of Federal Regulations, states may only impose cost sharing requirements up to a certain limit (5% is the maximum coinsurance amount). Therefore, we are unable to impose greater coinsurance amounts at this time.

COMMENT #22: Prescription amounts should be limited to only a 30-day supply.

RESPONSE: The Department has examined and plans to implement a

change to the day supply in the near future. We agree that because eligibility is determined monthly, it makes the most sense to limit prescriptions to only a 30-day supply.

COMMENT #23: Time limits should be placed on expensive medications, like Prilosec. After 90 days of therapy, a less expensive generic medication should be dispensed.

RESPONSE: In the next couple of months, the Department plans to implement a step therapy program for one expensive class of drugs, Proton Pump Inhibitors (PPIs). This step therapy will allow the Department to realize cost savings at the same time we will be better controlling the drug regimens of the large number of people taking those expensive medications. Additionally, the Department already requires prior authorization on a number of expensive medications and the mandatory generic substitution program requires prescribers and pharmacies to prescribe and dispense a generic form of a drug, whenever possible.

COMMENT #24: Initial prescriptions for expensive medications (particularly mental health drugs) should be limited in order to avoid expensive waste because of when a client must change dosages or strengths.

RESPONSE: The Department is also investigating the idea of limiting the day supply on certain classes of drugs, particularly mental health drugs. The Department hopes that by requiring smaller day supplies on drugs for which the strength often changes, we can realize cost savings and prevent waste of unused medications.

COMMENT #25: More strenuous education should be provided for physicians so they better understand how to save money, and physicians who do not cooperate should be dropped from Medicaid.

RESPONSE: The Department agrees that physician education is a key component to help contain costs in the pharmacy program. Although the Department does not have the authority to terminate a Medicaid provider based on their prescribing habits, the Department can target those providers and demand (by way of audits and information) changes in behavior.

COMMENT #26: Mandatory generic dispensing should be enacted and physicians should not be allowed to write "Dispense As Written" on a prescription.

RESPONSE: The Department has already instituted mandatory generic substitution (effective June 2001). However, physicians will always have the ability to indicate Dispense As Written and the Department can only control that dynamic by requiring prior authorization before Medicaid will pay for a brand name drug.

COMMENT #27: Direct-to-consumer advertising should be banned in the State of Montana because recipients are using that

information to demand unneeded drugs.

RESPONSE: The Department has no control over direct-to-consumer advertising in the State of Montana.

COMMENT #28: The Governor and the Governor's Budget Office do not understand the value of pharmacy in the total health care picture. These reductions may result in immediate savings but will not result in long term solutions.

RESPONSE: Although the Department cannot comment on the position of the Governor or her Budget Office, the Department does understand the positive impact pharmacotherapy has on the overall well being of any individual. Although optional under the federal requirements, Montana Medicaid has chosen to provide a pharmacy benefit because we recognize the benefit to all Medicaid recipients. Furthermore, the Department believes that we can achieve long term savings from the proposed changes to reimbursement and other program areas.

Dawn Sliva
Rule Reviewer

Director, Public Health and Human Services

Certified to the Secretary of State June 17, 2002.

Exhibit 6

Medicaid Source Survey Results

01/12/98jtc
Survey results:

Total number sent _____ (get information from Dorothy)
A total of 71 completed questionnaires were received after a single mailing with no follow-up. One questionnaire was incomplete and not used in the analysis. The remaining 70 questionnaires were analyzed to determine the sources used by Montana pharmacies to obtain a selected list of medications that are reimbursed at a direct order rate.

Respondent characteristics

Almost two-thirds of the respondents represented independent pharmacies (64 percent). The 'other' category of respondents included a home infusion and a mail-order pharmacy.

Table 1. Number of Respondents by Type of Practice (n = 70)

Type	# (%) responses
Independent	45 (64%)
Chain	12 (17%)
Grocery store	9 (13%)
Hospital	2 (3%)
Other	2(3%)
Total Responses	70 (100%)*

*Sum of percentages may not equal 100 due to rounding

Table 2. Number (Percent) of Respondents Using Each Source by Product Manufacturer (n = 70)[a]

Manufacturer of product	Direct	Wholesaler	Buying Group	Missing
Abbott	2 (3%)	69 (99%)	1 (1%)	
Upjohn	8 (11%)	63 (90%)	1 (1%)	
Wyeth	29 (41%)	45 (64%)	2 (3%)	
Pfizer 49	1 (1%)	67 (96%)	2 (3%)	1 (1%)
Pfizer 69	0	69 (99%)	2 (3%)	
Pfizer 662	0	69 (99%)	2 (3%)	
Pfizer 663	0	69 (99%)	2 (3%)	
Pfizer 995	0	69 (99%)	2 (3%)	
Lederle	11 (16%)	60 (86%)	1 (1%)	

[a] Row totals will sum to more than 100 percent because some respondents indicated more than one source per labeler code

How much are we spending on these labelers - what's the volume

Subset of Independent, Chain and Grocery store-based Pharmacies - Excluding hospital and "other" sites (n=4) left 66 sites described as independent or chain/grocery store-based pharmacies to be analyzed. The number of respondents obtaining products from direct or indirect sources are summarized in Table 3 and a breakdown of sources by independent or chain/grocery store-based sited is shown in Table 4.

Table 3. Number (Percent) of Respondents Using Each Source by Product Manufacturer (n = 66)[a]

Manufacturer of product	Direct	Wholesaler	Buying Group	Missing
Abbott	0	66	0	
Upjohn	8 (12%)	59 (89%)	0	
Wyeth	29 (44%)	41 (62%)	1 (2%)	
Pfizer 49	1 (2%)	63	1	1 (2%)
Pfizer 69	0	65	1	
Pfizer 662	0	65	1	
Pfizer 663	0	65	1	
Pfizer 995	0	65	1	
Lederle	11 (17%)	56 (85%)	0	

[a] Row totals may not sum to 100 percent because some respondents indicated more than one source per labeler code and due to rounding

Table 4. Number (Percent) of Respondents Using a Direct or Indirect Source by Product Manufacturer (n = 66)[a]

	Independent (n =45)		Non-Independent (n=21)	
Manufacturer	Direct	Indirect[b]	Direct	Indirect
Abbott	0	45	0	21
Upjohn	7 (16%)	39	1 (5%)	20
Wyeth	25 (56%)	23	4 (19%)	19
Pfizer 49	1 (2%)	44	0	20[c]
Pfizer 69	0	45	0	21
Pfizer 662	0	45	0	21
Pfizer 663	0	45	0	21
Pfizer 995	0	45	0	21
Lederle	9 (20%)	37	2 (10%)	19

[a] Sample analyzed includes 66 respondents:
Independents is same number (n = 45)
Non-independent is total of chain plus grocery store-based pharmacies (n = 21)
Hospital and "others" not included in subset (n = 4)
[b] Indirect sources include wholesalers and buying groups
[c] Missing one data point

Subset of respondents indicating NOT satisfied with at least one product source.

Sixty nine respondents sent sufficient information to analyze satisfaction with source. Respondents indicating complete satisfaction with all the sources used to obtain the targeted products (n = 33) were separated from the respondents with at least one NOT satisfactory response to a source (n =36). Table 5 shows the results of the analysis conducted on the remaining 36 respondents to determine how many used a direct source or a wholesaler and the reasons why the source was NOT satisfactory.

Table 5. Product and source by number of NOT satisfactory responses (n = 36)

	Total	Direct (total # and reasons)						Wholesaler (total # and reasons)						
		#	1[a]	2	4	5	6		1	2 (%)	3	5	6	7
Abbott	10	0						10	3	8 (80)				1
Upjohn	13	3	3	2	2	1		10	5	7 (70)		1		
Wyeth	7[b]	4	2	2	1	1	1	5	2	5 (100)		1	1	
Pfizer 49	11[c]	1		1				9	3	8 (89)	1	1		
Pfizer 69	11[c]	0						10	3	9 (90)	1	1		
Pfizer 662	11[c]	0						10	3	9 (90)	1	1		
Pfizer 663	11[c]	0						10	3	9 (90)	1	1		
Pfizer 995	11[c]	0						10	3	8 (80)				
Lederle	9[b]	3	1	1	1	1	1	7	2	6 (86)		1	1	

[a] Respondents could choose more than one reason for a NOT satisfied response. The options were:

1. Accessibility of the product (limited due to required minimum order size)
2. Medicaid reimbursement for the cost of the product
3. Costs of shipping and handling
4. Convenience of ordering
5. Timeliness of delivery
6. Customer service
7. Other - "return policy"

[b] One respondent indicated both direct and wholesaler source

[c] One respondent belonged to a buying group for Pfizer products

Of those respondents using a wholesaler to obtain the targeted products, the most frequently cited reason for not being satisfied with the source was "Medicaid reimbursement for the cost of the product."

MONTANA STATE PHARMACEUTICAL ASSOCIATION

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Jan. 29

Dorothy -

Lori asked me to send along the attached Survey Results & Article...

I'm not sure what all this "means" as how to follow up & make decisions based on these results. So... I'm very eager to get your comments & feedback.

Please give me a call once you've had a chance to review & consider this.

Thanks in Advance,

Jim Smith

Exhibit 7

DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES
HEALTH POLICY & SERVICES DIVISION

MARC RACICOT
GOVERNOR

LAURIE EKANGER
DIRECTOR

STATE OF MONTANA

COGSWELL BLDG., 1400 BROADWAY
PO BOX 202951
HELENA, MONTANA 59620-2951

April 15, 1999

Jim Smith
Montana State Pharmaceutical Association
PO Box 4718
Helena, MT 59604

Dear Jim:

As you know, the Pharmacy Coordinating Committee conducted a survey of pharmacies with the University of Montana School of Pharmacy and Allied Health Sciences to determine the extent to which pharmacies acquired drug products directly from manufacturers. The survey showed that responding pharmacies purchase through drug wholesalers rather than directly from manufacturers. As a result of this survey, the Committee asked that Medicaid consider changing its reimbursement methodology for those labelers that currently pay at the direct price to average wholesale price less 10%.

We now have an opportunity to implement a change in the direct price methodology. The 1999 Legislature has authorized a 1% provider increase for each year of the next biennium. I propose that we use this increase to fund a change in the reimbursement methodology.

I recently completed an analysis of the direct price manufacturers to determine the program cost of changing from direct price (DP) reimbursement to average wholesale price (AWP) less 10%. Using product utilization from 7/1/97 through 6/30/98, I calculated the cost difference between the two reimbursement methods using the most current rates for AWP and DP. These cost differences are an estimate of program cost because they do not take into account recipient copay, maximum allowable cost (MAC) pricing on generics, and differences in submitted charges. The results of this analysis are shown below.

As you can see, removing all the labels from direct price would result in an increased cost of approximately $335,868 per year. The amount available to the program for a provider increase is approximately $48,817 in the first year, and $99,391 in the second year for a total of $148,208 for the biennium. These amounts were calculated by applying the 1% increase in each year of the coming biennium to the pharmacy dispensing fee. (Calculation: 1,162,310 scripts x .042 + 1,183,232 scripts x .084)

PHONE: (406) 444-4540 FAX: (406) 444-1861

Label	AWP- 10%	Direct Price	Difference/Year
00005	$163,253	$146,954	$16,300
00008	$533,954	$479,977	$53,977
00009	$236,015	$209,561	$26,454
00662-00663	$3,363	$3,167	$196
00049	$1,434,053	$1,348,153	$85,900
00069	$805,650	$758,464	$47,186
00074	$1,749,271	$1,643,416	$105,855
TOTAL	$4,925,559	$4,589,692	$335,868

I propose that we phase in elimination of direct price reimbursement by removing labels 00005, 00008, 00009, 00662 and 00663 from this methodology for the 2000-2001 biennium. The analysis shows that this will result in approximately $193,854 greater cost to the Medicaid pharmacy program. If the legislature authorizes another provider increase next biennium, we would continue to eliminate the labels subject to direct price.

Please share this proposal with members of the Montana State Pharmaceutical Association and let me know if it is acceptable. If so, I will initiate the changes to become effective July 1, 1999. If you or anyone else have questions or comments, please feel free to contact me at (406) 444-2738 or dpoulsen@state.mt.us.

Sincerely,

Dorothy

Dorothy Poulsen
Pharmacy Program Officer
Medicaid Services Bureau

7.2.24.4
c: Mary Dalton, Jeff Buska